DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 5, 2014

Mortara Instrument, Inc
Amy Yang
Sr. Regulatory Affairs Engineer
7865 North 86th Street
Milwaukee, Wisconsin 53224

Re: K142105
Trade/Device Name: ELI 380 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: August 6, 2014
Received: August 7, 2014

Dear Amy Yang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

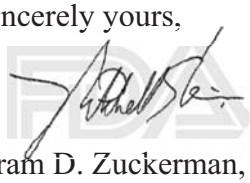
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142105

Device Name: **Mortara ELI 380 Electrocardiograph**

Indications for Use:

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Special 510(k) Notification

510(k): ELI 380 Electrocardiograph Device Summary

Submitter: **Date: July 29, 2014**

Amy Yang, Sr. Regulatory Affairs Engineer
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
FAX: (414) 354-4760
Phone: (414) 354-1600
Contact: Amy Yang (see above)

Trade Name:	ELI 380 Electrocardiograph
Common Name:	Electrocardiograph
Device:	Electrocardiograph
Regulation Description	Electrocardiograph
Regulation Number:	21 CFR 870.2340
Product Code:	DPS

Legally marketed devices to which S.E. is claimed:

Mortara ELI 380 Electrocardiograph	Predicate 510(k) Number	Predicate Manufacturer / Model
Mortara ELI 350 Electrocardiograph	K082946	Mortara Instrument, Inc. / ELI 380

The ELI 380 Electrocardiograph is an update to the ELI Series Electrocardiographs and is substantially equivalent to the ELI 350 Electrocardiograph (K082946) and other Mortara electrocardiograph devices presently in distribution.

Description:

The electrocardiogram (ECG) is a graphic description of the electrical activity of the heart. This activity is recorded from the body surface by a group of electrodes positioned at predefined places to reflect the activity from different perspectives. The cardiac data acquired and provided by the ELI 380 is used by trained medical personnel to assist in the diagnosis of patients.

The ELI 380 is a multichannel, high-performance resting interpretive electrocardiograph utilizing a large high resolution color LCD for display of ECG waveforms, menu options and status information. The LCD provides a preview of the ECG for the clinician to assess its quality. The overall design of the ELI 380 is a “clamshell” style where the LCD screen can be closed over the printer when the unit is shipped or not in use. The ELI 380 operates from an internal battery or AC power.

A full size keyboard is part of the ELI 380 design and allows patient data entry as well as control of the functions and options available for the unit. The keyboard includes alphabetic, numeric, symbol, cursor control, special function keys and integrated pointing device. The ELI 380 keyboard is constructed of a continuous surface of chemically strengthened glass permitting ease of cleaning and disinfection. The ELI 380 is designed to be installed on an optional transport cart.

The ELI 380 is able to acquire data via direct or wireless patient connection. Once the data is acquired it can be analyzed, reviewed, stored, printed or transmitted. The ELI 380 is able to retrieve and transmit stored records.

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Transmission can be achieved using one of the optional communication media designed in the unit: LAN, WLAN, and/or USB port.

The ELI 380 incorporates a full size thermal writer that allows printouts using several formats. The writer is also used for real time, continuous rhythm printouts at various speeds.

The ELI 380 offers, adult and pediatric interpretation capability to assist the physician over-read of the electrocardiogram. The ELI 380 maintains a running buffer and a condensed display allowing the user to identify a preferred 10 second sample to acquire. The ELI 380 can also suggest the "Best 10" second segment from the buffer based on the quality of the ECG.

Technology Comparison:

The Mortara ELI 380 Electrocardiograph utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use:

The ELI 380 is intended to be a high-performance, multichannel resting electrocardiograph. As a resting electrocardiograph, the ELI 380 simultaneously acquires data from each lead. Once the data is acquired, it can be analyzed, reviewed, stored, printed or transmitted. It is a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size.

Indications for Use:

The proposed Mortara ELI 380 Electrocardiograph is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

Performance Testing:

Sterilization Validation – The Mortara ELI 380 Electrocardiograph is not sterilized or sterilizable, and therefore this section does not apply to the Electrocardiograph itself.

Shelf Life Testing – The Mortara ELI 380 Electrocardiograph is not sterilized or sterilizable, and therefore this section does not apply to the Electrocardiograph itself.

Biocompatibility Testing – The electrodes, housing and patient cables are parts of the system that come in contact with the patient. These component devices have been previously tested in their own right for other submissions and found to be acceptable. However, the ELI 380 Electrocardiograph itself does not involve direct / indirect patient contact.

Software Testing – Software for the Mortara ELI 380 Electrocardiograph was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Mortara ELI 380 Electrocardiograph complies with its predetermined specification.

Electrical Safety – The Mortara ELI 380 Electrocardiograph was evaluated for patient safety in accordance with applicable Standards.

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Electromagnetic Compatibility Testing – The Mortara ELI 380 Electrocardiograph was tested for EMC in accordance with applicable Standards. Test results indicated that the Mortara ELI 380 Electrocardiograph complies with its predetermined specification.

Performance Testing – Bench – The Mortara ELI 380 Electrocardiograph was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional.

Performance Testing – Animal – Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara ELI 380 Electrocardiograph.

Performance Testing – Clinical - Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara ELI 380 Electrocardiograph.

Conclusion – Based upon a comparison of devices and performance testing results, the Mortara ELI 380 Electrocardiograph is substantially equivalent to the predicate device.